

I. REMARKS

Preliminary Remarks

Claims 9, 10, 26, and 27 will be pending, of which claim 27 is independent. No claims are amendeded, withdrawn, canceled, or added as a result of this response.

The applicants respectfully request entry of this response pursuant to 37 C.F.R. §1.116, in that if the examiner maintains the claim rejections, this response places the application in better form for appeal.

This response is filed within the shortened statutory period for response, with no fee due. The applicants respectfully request reconsideration and allowance of the present application.

Patentability Remarks

Rejections under 35 U.S.C. §103 –

Claim 9 was rejected under 35 U.S.C. §103(a) as unpatentable over Del Soldato *et al.* (WO 95/30641). The applicants respectfully traverse in view of the following remarks.

The examiner's argument appears to be that Del Soldato *et al.* disclose the genus of these compounds and, in the absence of unexpected results, it would have been obvious to select the specific specie claimed in claim 9. However, according to the Manual of Patent Examining Procedure (M.P.E.P.) §2144.08:

The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has "decline[d] to extract from *Merck & Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that... regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it."). See also *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995). (emphasis added).

...

To establish a *prima facie* case of obviousness in a genus-species chemical composition situation, it is essential that Office personnel find some motivation or suggestion to make the claimed invention in light of the prior art teachings. ... In order to find such motivation or suggestion there should be a reasonable likelihood that the claimed invention would have the properties disclosed by the prior art teachings. The prior art disclosure may be express, implicit, or inherent. Regardless of the type of disclosure, the prior art must provide some motivation to one of ordinary skill in the art to make the claimed invention in order to support a conclusion of obviousness. (emphasis added).

In other words, if a reference discloses a genus of compounds, the examiner has to show that there is some motivation in that reference to select a specific specie. While there is no absolute correlation between the size of the prior art genus and a conclusion of obviousness, it is relevant that Del Soldato *et al.* conservatively disclose thousands of compounds and does not provide any motivation to select the compound in claim 9.

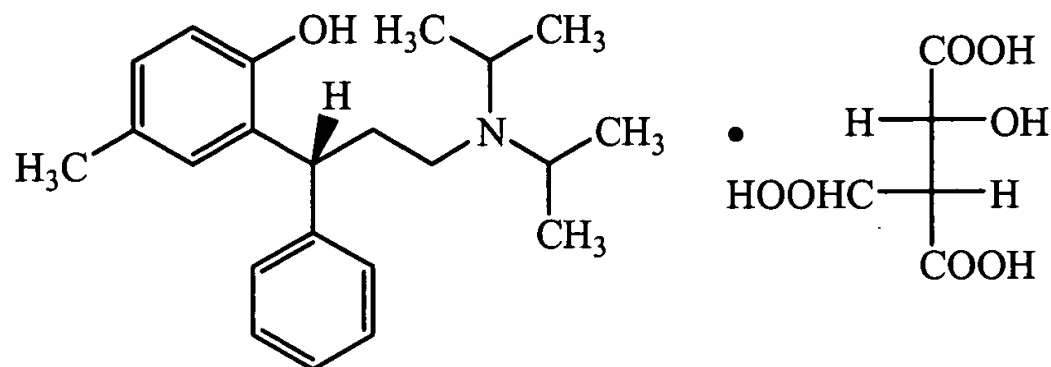
Therefore, the applicants respectfully submit that the examiner has not met his burden in showing that it would have been obvious to select the specie claimed in claim 9 over the thousands of compounds listed in Del Soldato *et al.* In other words, the applicants submit that claim 9 is not unpatentable over Del Soldato *et al.* and request withdrawal of this rejection.

Claims 10 and 27 were rejected under 35 U.S.C. §103(a) as unpatentable over Del Soldato *et al.* in view of Armour *et al.* (U.S. Pat. No. 5,703,240). The applicants respectfully traverse in view of the following remarks.

The examiner's argument appears to be that while Del Soldato *et al.* do not specifically teach that these compounds can treat urinary incontinence, Armour *et al.* teach that urinary incontinence is an inflammatory disorder and anti-inflammatory agents can be used to treat urinary incontinence.

However, even if urinary incontinence is an inflammatory disorder and while some anti-inflammatory agents can be used to treat urinary incontinence, not all anti-inflammatory agents can be used to treat urinary incontinence. For example, there is no evidence that aspirin and ibuprofen, two well-known anti-inflammatory agents have been used to treat urinary incontinence.

In addition, urinary incontinence can be, and is, successfully treated by compounds that are not anti-inflammatory agents. For example, the most common treatment for urinary incontinence is Detrol[®] (tolterodine tartrate) as shown. This compound is a muscarinic receptor antagonist and not an anti-inflammatory agent.



Detrol

In other words, at best it is obvious to try and combine Del Soldato *et al.* with Armour *et al.* However, can be no reasonable expectation of success because other anti-inflammatory agents (such as aspirin and ibuprofen) do not treat urinary incontinence while non-anti-inflammatory compounds (such as Detrol[®]) successfully treat urinary incontinence. Therefore, the applicants respectfully submit that claims 10 and 27 are not unpatentable over Del Soldato *et al.* in view of Armour *et al.* and request withdrawal of this rejection.


III. CONCLUSION

In view of the remarks above, the applicants respectfully submit that this application is in condition for allowance and request favorable action thereon.

In the event this response is not timely filed, the applicants hereby petition for an appropriate extension of time. The fee for this petition, along with any additional fees required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 026220-00031.

Respectfully submitted,

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